

REMARKS

Applicant thanks the Examiner for the telephonic interview on December 18, 2002, with the undersigned and William Coffey. Applicant believes that the telephonic interview was helpful in clarifying the issues and advancing prosecution of this matter.

The specification at page 11 has been amended to correct a typographical error. Support for this amendment is found on page 8, lines 15-16. Claim 1 has been amended for clarification purposes and to specify that the collagen matrix is for integration into the wound. Support for this amendment is found in the specification, for example on page 7, lines 17-19; page 11, lines 7-14, and in claim 35 as originally filed. Claim 16 has been amended to provide proper antecedent basis. Claim 27 has been amended to clarify that the vacuum generated is sufficient to begin integration of the collagen matrix into the wound surface. Support for this claim amendment is found in claim 35 as originally filed. Claim 35 has been amended for consistency with the amendment to claim 27, from which claim 35 depends. No new matter has been added by way of these amendments. A marked up copy of the amendment to the specification is provided as Appendix A and a marked up copy of the amendments to the claims is provided as Appendix B.

Claims 1, 2, 8, 9, and 14-18 stand rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention. The Examiner notes that claim 1 recites "collagen matrix formed" but that the specification does not teach forming the collagen at the wound site. Claim 1 has been amended to remove the recitation "formed." Claims 2, 8, 9, and 14-18 depend from claim 1. Accordingly, applicant respectfully requests withdrawal of this rejection.

Claim 16 stands rejected as indefinite. According to the Examiner, claim 16 describes that the semi-rigid wall of the structure has a lower member that is adjacent to the patient's skin surrounding the wound, and that a review of the figures and disclosure shows that the structure is not adjacent to the skin and instead is above the collagen layer, which in turn is adjacent the patient's skin. Applicant respectfully refers the Examiner to Fig. 5. The specification at page 9, lines 6-7 describes that "[s]emi-rigid dome 320 includes a lower member 322 adapted to lie adjacent the patient's skin surrounding wound 12." As seen in Fig. 5, in this embodiment the collagen layer 14 does not extend beyond the wound 12, and the semi-rigid dome 320 is not in contact with the collagen layer 14. Clearly, the lower member 322 of semi-rigid dome 320 is in contact with the patient's skin 24 and the subject matter of claim 16 is fully

supported by the embodiment illustrated in Fig. 16. Thus, applicant respectfully requests withdrawal of this rejection.

Claims 16 and 33 stand rejected as indefinite due to the recitation of "spaced-apart relationship." According to the Examiner, the instant disclosure does not provide any description of the positions of the collagen and the structure that reflects the claimed spaced apart relationship, other than showing the collagen matrix in direct contact with the wound, over which is placed the structure and covered by a wound cover. The "spaced-apart" relationship in claim 16 describes the relationship between the upper member of the semi-rigid structure and the collagen matrix, and in claim 33 the semi-rigid wall is spaced apart from the collagen matrix. Again, applicant respectfully refers the Examiner to Fig. 5. As shown in Fig. 5, neither the upper member 324 nor the wall 326 of the semi-rigid structure 320 are in contact with the collagen matrix. Therefore, the semi-rigid structure (upper member or wall) is in a spaced-apart relationship from the collagen matrix. Applicant respectfully requests withdrawal of this rejection.

Claim 16 stands rejected because there is insufficient antecedent basis for "SIS layer" in lines 3 and 6. Claim 16 has been amended to replace the term "SIS layer" with "collagen matrix." Claim 1 provides proper antecedent basis for the "collagen matrix" of claim 16. Accordingly, applicant respectfully requests withdrawal of this rejection.

Claims 1-2, 8-9, 14-18, 27-28, 30-37, and 39-43 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,759,354 to Quarfoot in view of U.S. Patent No. 5,645,081 to Argenta. According to the Examiner, Quarfoot teaches a wound dressing comprising a layer of collagen for placement directly over the wound, absorbent adhesive layer for adhering the wound dressing to the skin, and a thin outer vapor permeable layer, where the absorbent layer extends beyond the periphery of the collagen layer such that it acts as a reservoir for the wound exudates. The Examiner finds that Argenta teaches an apparatus that comprises a vacuum means for creating a negative pressure on the area of tissue surrounding the wound, sealing means operatively associated with the vacuum means to maintain negative pressure on the wound, and a screen means to prevent overgrowth of tissue in the wound area. The screen means comprises a section of open-cell foam, which is porous and configured to be placed over the wound.

The Examiner acknowledges that Quarfoot does not teach that the wound cover is adapted for communication with a vacuum source, and that Quarfoot also differs from the instant claims in teaching a structure for placement between the collagen matrix and cover, which is

configured to provide a vacuum space. However, the Examiner concludes that it would have been obvious for one of ordinary skill in the art at the time of the instant invention to modify the wound dressing of Quarfoot by including a porous, semi-rigid screen structure and attaching it to a vacuum means through a hose or tube, so as to apply a negative pressure to the wound.

Applicant respectfully disagrees with the Examiner's conclusion. Quarfoot teaches a unitary or composite wound dressing. See Col. 5, lines 10-20. The wound dressing of Quarfoot combines the healing properties of collagen and the water-absorptive properties of materials such as hydrogels into a single unitary dressing. The dressing is applied to the wound and subsequently removed. Col. 7, line 6. It would be difficult to modify the unitary dressing of Quarfoot by adding a semi-rigid screen structure between the collagen matrix and cover, to provide a vacuum space. If the screen is placed between the collagen and the hydrogel, it is unclear how the hydrogel would function. If the screen is placed between the hydrogel and the cover, it is unclear how the negative pressure would be maintained on the wound itself. Furthermore, while collagen and other materials having healing properties were known, Argenta teaches that healing occurs at a faster rate with only reduced pressure and placing the screen means in the wound. Thus, Argenta teaches away from the asserted combination. Additionally, claim 27 requires sufficient vacuum to draw blood from the wound into the collagen matrix. Neither Quarfoot nor Argenta teach that blood from a wound should be drawn into a collagen matrix.

Moreover, as discussed in the specification at page 7, lines 17-19 and page 11, lines 7-14, the collagen layer of the present invention becomes integrated in the wound and is restructured to resemble the surrounding tissue. The unitary dressing of Quarfoot is entirely unsuited for this remodeling. If the collagen layer of Quarfoot gets integrated into the wound, removal of the dressing would create a new wound. In an effort to expedite prosecution of this case, claims 1 and 27 have been amended to clarify that the collagen is for integration into the wound. In the telephonic interview of December 18, 2002, the Examiner agreed that such claim amendments would distinguish the rejected claims from Quarfoot and Argenta. Thus, withdrawal of this rejection is respectfully requested.

Claims 6 and 7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,759,354 to Quarfoot in view of U.S. Patent No. 5,645,081 to Argenta, and further in view of U.S. Patent No. 6,440,427 to Wadstrom. The Examiner notes that the wound dressings of Quarfoot and Argenta lack the fibrin glue of claims 6 and 7. According to the

Examiner, Wadstrom teaches fibrin sealants and that such fibrin sealants are used in a number of fields, especially for wound healing and prevention of adhesion of adjacent tissues.

While applicant acknowledges that Wadstrom teaches that fibrin sealants may be used for wound healing, Wadstrom fails to overcome the deficiencies discussed above, with respect to Quarfoot and Argenta. Accordingly, applicant respectfully requests withdrawal of this rejection.

Finally, if the Examiner finds claims 1 and 27 to be allowable, applicant requests reconsideration of the restriction requirement. Small intestine submucosa (SIS) is a species of the genus of collagen matrices.

CONCLUSION

The application is believed to be in condition for allowance. Withdrawal of the rejection and passage of the application to issuance is respectfully requested.

Respectfully submitted,
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Appendix A
Version with markings to show changes made

Under 37 C.F.R. § 1.121(b), please amend the paragraph beginning on page 11, line 15, as follows:

Thus, in one embodiment the present invention is a method for treating wounds comprising the steps of preparing the wound surface, applying a bandage to the wound, the bandage having an SIS layer secured over the wound and a cover above the wound and the SIS layer to define a vacuum space between the [wound] cover and SIS layer, and applying suction to the vacuum space to draw blood from the wound into the SIS layer.

Appendix B
Version with markings to show changes made

Under 37 C.F.R. § 1.121(c)(1)(i), please amend claims 1, 16, 27, and 35 as follows:

1. (Amended) A wound care bandage comprising:

- (a) a collagen matrix [formed] for placement on and integration into a wound,
- (b) a cover configured for placement over the wound to provide a sealed environment around the wound and adapted for communication with a vacuum source, and
- (c) a structure for placement between the collagen matrix and the cover and configured to provide a vacuum space.

16. (Amended) The bandage of claim 15, wherein the semi-rigid wall includes a lower member adapted to lie adjacent a patient's skin surrounding the wound, an upper member configured to remain in a spaced-apart relationship from the [SIS layer] collagen matrix, and a middle member integrally coupled to the upper and lower members, the middle member provided to support the upper member in the spaced-apart relationship with the [SIS layer] collagen matrix.

27. (Amended) A method for promoting wound healing comprising the steps of:

- (a) applying a first collagen matrix to a wound surface,
- (b) creating a vacuum space in communication with the wound and the first collagen matrix, and
- (c) generating a vacuum within the vacuum space in a magnitude and duration sufficient to draw blood from the wound into the first collagen matrix and to begin integration of the first collagen matrix into the wound surface.

35. (Amended) The method of claim 27, [wherein the vacuum is generated for a sufficient period of time to begin integration of the first collagen matrix into the wound surface, and] further comprising the step of placing a second collagen matrix over the location of the first collagen matrix.